

Serial No. 10/602,215
PC 21501B

Please replace all prior claims in the application with the following:

Claim 1 (currently amended): A liquid pharmaceutical composition ~~of comprising~~ a gamma-aminobutyric acid (GABA) GABA analog comprising at least one polyhydric alcohol and one or more polyhydric alcohols, each containing 2 to 6 carbon atoms, wherein the one or more polyhydric alcohols comprise about 25% to about 75% weight/volume of the composition and ~~wherein said the~~ composition has a pH of about 5.5 to about 7.0.

Claim 2 (currently amended): The composition according to claim 1, wherein the one or more polyhydric alcohols each polyhydric alcohol contains 3 to 5 carbon atoms and ~~wherein the content of polyhydric alcohol is about 25% to about 75% weight/volume (w/v).~~

Claim 3 (currently amended): The composition according to claim 2, wherein the one or more polyhydric alcohols are polyhydric alcohol is selected from the group consisting of: glycerol, xylitol, sorbitol, mannitol, and a mixture of glycerol and xylitol, and wherein the one or more polyhydric alcohols comprise content of polyhydric alcohol is about 40% to about 75% weight/volume (w/v) of the composition.

Claim 4 (original): The composition according to claim 1, wherein the pH is about 6.0 to about 7.0.

Claim 5 (currently amended): The composition according to claim 1, comprising one or both of: ~~(a) an additional a preservative; and (b) an additional a flavor improver,~~ wherein the flavor improver which does not contain an aldehyde or keto functionality.

Claim 6 (currently amended): A method for preparing a liquid pharmaceutical composition ~~of a GABA analog comprising:~~ Step (1) adding one or more polyhydric alcohols, each a polyhydric alcohol containing 2 to 6 carbon atoms, to water to form a first solution; Step (2) adding a gamma-aminobutyric acid GABA analog to the first solution from Step (1) to form a second solution; and Step (3) optionally, adjusting the pH of the second solution composition to about 5.5 to about 7.0 to afford the liquid

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pharmaceutical composition, wherein the one or more polyhydric alcohols comprise about 25% to about 75% weight/volume of the composition.

Claim 7 (currently amended): The method according to claim 6, wherein the one or more polyhydric alcohols are polyhydric alcohol is a mixture of glycerol and xylitol.

Claim 8 (currently amended): The method according to claim 6, wherein the content of polyhydric alcohol is about 25% to 75% (w/v) and the pH of the composition is about 6 to about 7.

Claim 9 (currently amended): A ~~two-component~~ liquid pharmaceutical composition of a ~~GABA analog~~ comprising (a) a first component, the first component comprising a powder mixture of a gamma-aminobutyric acid (GABA) GABA analog and a one or more solid polyhydric alcohols alcohol; (b) ~~and~~ a second component comprising a liquid base, wherein the powder first and second components are combined component from (a) is added to the liquid base from (b) to afford a the liquid pharmaceutical composition in which the one or more polyhydric alcohols comprise about 25% to about 75% weight/volume of the composition.

Claim 10 (currently amended): A method for preparing a ~~two-component~~ liquid pharmaceutical composition, the method of a GABA analog comprising: Step (1) mixing a gamma-aminobutyric acid (GABA) GABA analog with a first solid polyhydric alcohol to afford a powder mixture; Step (2) mixing a second polyhydric alcohol with a sweetener and a flavor in water to afford a liquid base; and Step (3) adding the powder mixture to the liquid base to afford the liquid pharmaceutical composition, wherein the first and second polyhydric alcohols may be the same or different and together comprise about 25% to about 75% weight/volume of the composition.

Claim 11 (original): The method according to claim 10, wherein the GABA analog is gabapentin or pregabalin.

Claim 12 (original): The composition according to claim 1 or claim 9 wherein the GABA analog is gabapentin or pregabalin.

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Claim 13 (currently amended): The composition according to claim 1 or claim 9 wherein said the composition has less than 0.5% by weight of the corresponding lactam of the GABA analog.

Claim 14 (currently amended): ~~An aqueous oral~~ A liquid pharmaceutical composition comprising of gabapentin or pregabalin, water, and one or more polyhydric alcohols, each characterized by a content of at least 25% (w/v) of at least one polyhydric aliphatic alcohol containing 2 to 6 carbon atoms, the composition having and a pH of about 5.5 to about 7.0 and containing, less than 0.5% weight/volume (w/w) of gabapentin lactam or pregabalin lactam, respectively, after storage at 2°C to 10°C to 110°C for 18 months to 2 years, wherein the one or more polyhydric alcohols comprise at least 25% weight/volume of the composition.

Claim 15 (currently amended): ~~The pharmaceutical composition according to claim 1 or claim 13 for the treatment of~~ A method of treating a subject suffering from cerebral diseases, including epilepsy, faintness attacks, hypokinesia and cranial traumas, neurodegenerative disorders, depression, mania and bipolar disorders, anxiety, panic, inflammation, renal colic, insomnia, gastrointestinal damage, incontinence, pain, including neuropathic pain, muscular pain, skeletal pain, and migraine, the method comprising administering to the subject a therapeutically effective amount of the pharmaceutical composition according to claim 1 or claim 13.

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